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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,798	12/05/2005	John E. Hunt	SPRUSON-09811	9386

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,798	HUNT ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,9,10,12-23 and 34* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 12-23* is/are withdrawn from consideration.

5)☒ Claim(s) *34* is/are allowed.

6)☒ Claim(s) *1-3 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/05/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed on 01/25/2008, are acknowledged.

Claims 4 – 5, 7 – 8, 11, and 24 – 33 have been canceled.
Claim 34 has been added.

Claims 1 – 3, 6, 9 – 10, 12 – 23, and 34 are pending.

2. Applicant's election without traverse of Group I (claims 1 – 3, 6, and 34) in the reply filed on 01/25/2008 is acknowledged.

Applicant further elected the species of SEQ ID NO:2 and rheumatoid arthritis.

Claims 9 – 10 and 12 – 23 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1 – 3, 6, and 34 are presently under consideration.

3. Receipt is acknowledged of foreign priority papers (Australian Application No. 2002951912) submitted under 35 U.S.C. 119(a)-(d), which papers are of record in the file of the instant application.

4. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 – 3 and 6 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for purified delta tryptase polypeptide comprising the amino acid sequence of SEQ ID NO:1, 2, or 3, does not reasonably provide enablement for the generically recited "fragment or analog thereof," "variant generated by alternative splicing," or variant "including one or more conservative amino acid substitutions." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to make and use the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The instant specification discloses three delta tryptase sequences, SEQ ID NO: 1, 2, and 3. The specification further discloses at page 7 that a "fragment" refers to a constituent of the full-length polypeptide which possesses qualitative biological activity of the full-length polypeptide, without any direction to the functionally important regions of the molecule or size limitation. The specification further defines "analogue" as a

derivative obtained by addition, deletion, or substitution of one or more amino acids (*ibid*), without direction as to the identity or number of amino acids which may be altered so that the polypeptide retain the function of delta tryptase. Likewise, Applicant has disclosed a single example of an alternative splicing variant of delta tryptase, SEQ ID NO:3, and no direction as to the structures of any of the potentially large number of other possible splice variants. It is noted that a variant generated by alternative splicing may potentially contain amino acid sequences which are not related to the instantly sequences.

Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

In view of this unpredictability, the skilled artisan would not reasonably expect a generically recited "fragment or analog," or variant "including one or more conservative amino acid substitutions" to possess the same function as the polypeptide of SEQ ID NO:1, 2, or 3, and there is insufficient guidance to direct the skilled artisan to such functional sequences. Thus the generic recitation of fragments, analogs, and variants does not allow the skilled artisan to make and use a polypeptide commensurate in scope with the instant claims without undue experimentation.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970). "It is not sufficient to

define the recombinant molecule by its principal biological activity, [...] because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

6. The following is a quotation of **35 U.S.C. 103(a)** which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 – 3 and 6 rejected under **35 U.S.C. 103(a)** as being obvious over Pallaoro et al. (J. Biol. Chem., 1999, 274: 3355 – 3362; of record – cited on IDS; see entire document).

Pallaoro et al. teach the nucleotide sequence and the predicted amino acid sequence of human mMCP-7-like tryptase (e.g. figure 5 at page 3360), which is 100% identical in amino acid sequence to the instantly recited SEQ ID NO:1, 99.7% identical to SEQ ID NO:2, and 98.8% identical to SEQ ID NO:3, as evidenced by the attached alignment. As such, the sequence taught by Pallaoro et al. constitutes a an analog or variant of the instantly recited SEQ ID NOS: 2 and 3.

Pallaoro et al. further teach that tryptases are implicated in asthma (e.g. the Abstract).

Pallaoro et al. do not teach a purified or expressed human mMCP-7-like polypeptide.

However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to express and purify the human mMCP-7-like polypeptide, given the nucleotide sequence taught by Pallaoro et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so, in view of the potential importance of the polypeptide in asthma, as taught by Pallaoro et al., and have a reasonable expectation of success, because of the routine nature of the experimentation involved.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claim 34 is allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI, Ph.D./
Primary Examiner, Art Unit 1644
May 15, 2008